

# REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: MEZI 100 SC

Product name(s): Rumezo Twist 100 SC,

Malton Twist 100 SC

Chemical active substance(s):

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorisation)

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023, **October 2024**

**RMS Assessment: 24/07/2024**

**Following commenting period: 21/10/2024**

## Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update

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Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Calisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Calisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- There are no data on analysing relevant impurities (R287431, R287432, 1,2-dichloroethane) of active substance Mesotrione in the PPP in the ambient two years storage stability study. Adequate data should be submitted by the applicant. Nevertheless, the missing data may be evaluated in the post registration at national level.

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: INNVIGO Sp. Z o.o.  
Address: INNVIGO Sp. z o.o.  
ul. Aleje Jerozolimskie 178,  
02-486 Warszawa

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

#### **1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)**

##### **1.2.3.1 Mesotrione**

According to the SANTE/11654/2016 final 23 March 2017

Mesotrione min. 920 g/kg

R287431 max. 2 mg/kg

R287432 max 2 g/kg

1,2-dichloroethane

max 1 g/kg

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Rumezo Twist 100 SC,  
Malton Twist 100 SC

Company code number: MEZI 100 SC

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Mesotrione	100 g/L	100 g/L ± 10	103.09 g/L	9.11%

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

\*\* Based on the density of the formulation = 1.098 (Note: only applies if a liquid formulation – delete this comment if not needed)

**Table 1.4-2: Safener and synergists**

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
N/A				

\* Based on the minimum purity of the safener/synergist declared for registration

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
Confidential information or data are provided separately (Part C).	

#### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-4: Information on Mesotrione**

Type	Name/Code Number
ISO common name	Mesotrione

Type	Name/Code Number
CAS No.	104206-82-8
EC No.	609-064-00
CIPAC No.	625

### **1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

CONFIDENTIAL information is provided separately (Part C).

### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Suspension concentrate

[Code: SC]

### **1.6 Function (KCP 1.6)**

Herbicide

## **2                    Section 2: Physical, chemical and technical properties of the plant protection product**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that homogenous and light-brown liquid with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has not a flash point It has a self-ignition temperature of 376°C. In aqueous solution, it has a pH value around 2.75 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE material. Its technical characteristics are acceptable for a SC formulation.

### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

No Classification is necessary

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

Not required

### **Compliance with FAO specifications:**

The product MEZI 100 SC complies with FAO specifications.

### **Formulation used for tests**

Not required

**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection, nasal inhalation	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 ID No: Date of production: 09.2020 Batch No: CHR/12	<b>Initial preparation:</b> Homogenous (at the beginning 10% v/v surfactants solution, homogeneous after stirring) light-brown liquid with a characteristic odour  <b>After accelerated storage:</b> Homogenous (at the beginning 5% v/v surfactants solution, homogeneous after stirring) light-brown liquid with a characteristic odour	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b>
	Visual and organoleptic test	99.5 g/L mesotrione SC (A12739A)	Yellow-brown liquid with an octanol like odour	N	Registration report of Callisto 100 SC Khot S. 2012 A12732A_10006	<b>Accepted</b>
Explosive properties (KCP 2.2.1)	EC A.14	Name of test item: MEZI 100 SC Active ingredient: Mesotrione A.I. CAS: - Date of production: 09.2020 Batch No: CHR/12	No explosive properties.	Y	Ołowski G., Study code: BW-07/23	<b>Accepted</b> Based on the result of impact sensitivity and thermal sensitivity the product does not have explosive properties.
Oxidizing properties (KCP 2.2.2)	Test UN O.2	Name of test item: MEZI 100 SC Active ingredient: Mesotrione A.I. CAS: -	No oxidizing properties	Y	Pachnicki P., Study code: BC-31/23	<b>Accepted</b> Based on the results of test UN O.2 the product does not have oxidising properties.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Date of production:09.2020 Batch No: CHR/12				
	UN Test O.2	9.06 % w/w mesotrione SC (A12739A)	Not an oxidising substance	Y	Registration report of Callisto 100 SC Jackson W.A. 2017 A12739A_11137	Accepted
Flash point (KCP 2.3.1)	SPO/BC/09/b (7 edition)	Name of test item:MEZI 100 SC Active ingredient: Mesotrione A.I. CAS: - Date of production:09.2020 Batch No: CHR/12	No auto-ignition temperature (boiling at 97°C) MEZI 100 SC.	Y	Pachnicki P., Study code: BC-31/23	Accepted
	ASTM D93-08 for Pensky-Martens closed cup testing	9.06 % w/w mesotrione SC (A12739A)	Not detected below 104°C	Y	Registration report of Callisto 100 SC Jackson W.A. 2017 A12739A_11137	Accepted
Flammability (KCP 2.3.2)	ASTM D93-08 for Pensky-Martens closed cup testing	9.06 % w/w mesotrione SC (A12739A)	Not classified as a flammable liquid	Y	Registration report of Callisto 100 SC Jackson W.A. 2017 A12739A_11137	Accepted
Self-heating (KCP 2.3.3)	SPO/BC/09/b (7 edition)	Name of test item:MEZI 100 SC Active ingredient: Mesotrione	Auto-ignition temperature of MEZI 100 SC is 376°C.	Y	Pachnicki P., Study code: BC-31/23	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		A.I. CAS: - Date of production:09.2020 Batch No: CHR/12				
	EEC A.15	99.5 g/L mesotrione SC (A12739A)	The auto-flammability of A12739A was measured as 420 ± 5 °C.	Y	Registration report of Callisto 100 SC Jackson W.A. 2017 A12739A_11137	<b>Accepted</b>
Acidity and pH (KCP 2.4.1)	CIPAC MTT 75.3 CIPAC MTT 191	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione	<b>Initial preparation:</b> pH: 2.25 Acidity: 3.75%	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> The pH was determined at 20°C. Due to pH less than 4, the acidity was tested.
	CIPAC MTT 75.3 CIPAC MTT 191	A.I. CAS: 104206-82-8 Date of production:09.2020 Batch No: CHR/12	<b>After accelerated storage:</b> pH: 2.22 Acidity: 3.74%			
	CIPAC MT 191 CIPAC MT 75.3	99.5 g/L mesotrione SC (A12739A)	The acidity of A12739A calculated as H2SO4 is 2.57 %. The pH of A12739A undiluted is 2.8 (at 25oC).	Y	Registration report of Callisto 100 SC Khot S. B. 2012 A12732A_10008	<b>Accepted</b>
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8	<b>Initial preparation:</b> 2.75	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> The pH was determined at 20°C.
			<b>After accelerated storage:</b> 2.72			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Date of production: 09.2020 Batch No: CHR/12				
	CIPAC MT 75.3	99.5 g/L mesotrione SC (A12739A)	The pH of a 1 % suspension of A12739A in water is 2.9 (at 25°C).	Y	Registration report of Callisto 100 SC Khot S. B. 2012 A12732A_10008	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192	99.5 g/L mesotrione SC (A12739A)	The dynamic viscosity of A12739A was measured at 20 and 40°C for the shear rate range 20 to 80 s <sup>-1</sup> At 20°C ± 0.5°C: 576 mPa s to 756 mPa s Shear rate: 80 to 20 s <sup>-1</sup> At 40°C ± 0.5°C: 244 mPa s to 402 mPa s Shear rate: 80 to 20 s <sup>-1</sup> The results demonstrate that A12739A is a non-Newtonian liquid.	Y	Registration report of Callisto 100 SC Khot S. B. 2012 A12732A_10008	Accepted
Surface tension (KCP 2.5.2)	EEC A.5	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production: 09.2020 Batch No: CHR/12	0.075% 29.21 mN/m 0.05% 31.05 mN/m 0.5% 27.14 mN/m 0.75% 26.13 mN/m 1 % 24.17 mN/m 5% 22.43 mN/m	Y	Arévalo E. Study code: BF-49/20	Accepted The surface tension is below 60 mN/m, the product is surface active.
	EEC A.5	99.5 g/L mesotrione SC (A12739A)	The surface tension ( $\sigma$ ) of A12739A was measured at 20 °C at a range of aqueous concentrations: $\sigma$ = 29.1 mN/m undiluted $\sigma$ = 24.4 mN/m 0.75 % w/v $\sigma$ = 27.8 mN/m 0.3 % w/v $\sigma$ = 29.7 mN/m 0.1 % w/v	Y	Registration report of Callisto 100 SC Khot S. B. 2012 A12732A_10008	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments	
			The results demonstrate that A12739A is a surface active material.				
Relative density (KCP 2.6.1)	CIPAC MT 3.2	Name of test item: CHR/H/MEZZO 100 SC Active ingerdient: Mesotrione A.I. CAS: 104206-82-8 Date of produc-tion:09.2020 Batch No: CHR/12	relative density 1.098 g/ml	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> The average measured absolute density of the initial preparation at 20°C was 1.098 g/ml and the calculated relative density at 20°C was 1.098.	
	OECD 109	99.5 g/L mesotrione SC (A12739A)	The relative density of A12739A was measured at 20°C ± 0.5°C: 1.095 g/ml	Y	Registration report of Callisto 100 SC Halarnakar R. 2012 A12732A_10001	<b>Accepted</b>	
Bulk density (KCP 2.6.2)	Not required for this formulation					<b>Accepted</b>	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	-	-	A12739A demonstrates some sensitivity to high temperature storage (54°C).Therefore the stability was determined after storage at 40 °C for 8 weeks.	-	-		
	Physical state colour and odour CIPAC MT 75.3  CIPAC MT 191 CIPAC MT 160	Name of test item: CHR/H/MEZZO 100 SC Active ingerdient: Mesotrione A.I. CAS: 104206-82-8 Date of produc-tion:09.2020 Batch No: CHR/12	After accelerated storage		Y	Arévalo E. Study code: BF-49/20	<b>Accepted*</b> The product is stable after 2-weeks stability test at 54°C.  *The following information are missing in the final report: - information about package material. There is only the following information “original
			Test type	Method			
			Physical state colour and odour	Physical state colour and odour	Homogenous (at the begin-ning 5% v/v surfactants solution, ho-mogeneous		

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																																												
	CIPAC MT 185 CIPAC MT 148.1 HPLC/DAD detector		<table><tr><td colspan="2"></td><td></td><td>after stirring) light-brown liquid with a characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>1%</td><td rowspan="2">CIPAC MT 75.3</td><td>2.72</td></tr><tr><td>undiluted</td><td>2.22</td></tr><tr><td colspan="2">Acidity</td><td>CIPAC MT 191</td><td>3.74%</td></tr><tr><td colspan="2">Dispersion spontaneity</td><td>CIPAC MT 160</td><td>72.01 %</td></tr><tr><td rowspan="6">Suspension stability</td><td>0.075%</td><td rowspan="6"></td><td>101.22%</td></tr><tr><td>0.05%</td><td>100.42%</td></tr><tr><td>0.5%</td><td>80.87%</td></tr><tr><td>0.75%</td><td>86.48%</td></tr><tr><td>1%</td><td>80.94%</td></tr><tr><td>5%</td><td>80.19%</td></tr><tr><td colspan="2">Wet sieve test</td><td>CIPAC MT 185</td><td>0.00%</td></tr><tr><td colspan="2">Pourability</td><td>CIPAC MT 148.1</td><td>R = 4.57%, R' = 0.71%</td></tr><tr><td colspan="2">Active ingredient content</td><td>HPLC/DAD detector</td><td>9.01% (98.90 g/l)</td></tr></table>						after stirring) light-brown liquid with a characteristic odour	pH	1%	CIPAC MT 75.3	2.72	undiluted	2.22	Acidity		CIPAC MT 191	3.74%	Dispersion spontaneity		CIPAC MT 160	72.01 %	Suspension stability	0.075%		101.22%	0.05%	100.42%	0.5%	80.87%	0.75%	86.48%	1%	80.94%	5%	80.19%	Wet sieve test		CIPAC MT 185	0.00%	Pourability		CIPAC MT 148.1	R = 4.57%, R' = 0.71%	Active ingredient content		HPLC/DAD detector	9.01% (98.90 g/l)			package”, - stability of packaging and packaging/preparation interactions (observation of pack stability including weight change. Indicate if there is any seepage of solvent through the container walls or seal).
			after stirring) light-brown liquid with a characteristic odour																																																	
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Active ingredient content		HPLC/DAD detector	9.01% (98.90 g/l)																																																	
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3 Determination of the a.s. content in the formulation: analytical method SF-424/1.	99.5 g/L mesotrione SC (A12739A)	A12739A undergoes no significant physical or chemical degradation during storage at 40°C in HDPE for 8 weeks.			N	Registration report of Callisto 100 SC Kundel P. 2012 A12739A_10446	Accepted																																												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	HPLC/DAD detector	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production: 09.2020 Batch No: CHR/12	<b>Initial preparation:</b> 9.22% (101.20 g/l)	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> The analytical method which was used to determine active ingredient (Mesotrione) content was validated in GLP laboratory (in-house methodology). Analytical method used for analysing a.s. in the PPP was validated in accordance with SANCO/3030/99 rev.5). The content of active substance - Mesotrione in the examined sample was determined by High Performance Liquid Chromatography (HPLC) using reversed phase column with DAD detector at wavelength measuring 220 nm and external standard.
			<b>After accelerated storage:</b> 9.01% (98.90 g/l)			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 184.1	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production:09.2020 Batch No: CHR/12	<b>Suspension stability after low temperature storage</b>	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> After the test period elapsed the samples were observed for their transparency, homogeneity and if any color change took place immediately after storage at 0±2°C, at room temperature and after 24 hours at room temperature and one inversion. The results of observations: homogenous liquid.  Suspensibility and wet sieve test were determined after storage. Suspensibility: the content of active substance - Mesotrione - in suspension was determined by High Performance Liquid Chromatography (HPLC) using reversed phase column with DAD detector at wavelength measuring 220 nm and external standard. The method was developed and validated in GLP	
			0.075%				96.05%
			0.05%				101.57%
			0.5%				89.15%
			0.75%				91.05%
			1%				90.97%
			5%				89.40%
			Wet sieve test in After low temperature storage:0.00%				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						laboratory. Acceptable limits:the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met.  Wet sieve test: Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
	CIPAC MT 39.3 CIPAC MT 185 CIPAC MT 184 CIPAC MT 160	99.5 g/L mesotrione SC (A12739A)	The effect of low temperature storage on the stability of A12739A was investigated. After 7 days storage at 0°C: There was no separation of A12739A. After 24 hours standing at room temperature and after 1 inversion there was no separation of A12739A. Tests were then performed using A12739A stored for 7 days storage at 0°C: Wet sieve test 75 µm sieve: <0.01 % retained Suspensibility (gravimetric determination) in CIPAC water D at 30°C: Concentration 0.75 %: 78 % Concentration 0.3 %: 92 % Spontaneity of dispersion (gravimetric determination): 88 %	N	Registration report of Callisto 100 SC Khot S.B. 2012 A12732A_10006	<b>Accepted</b>
Ambient temperature shelf life	GIFAP monograph 17 Determination of	99.5 g/L mesotrione SC (A12739A)	A12739A undergoes no significant physical or chemical degradation during storage at 20°C in HDPE for two years. The relevant impurity R287431 and R287432 may	N	Registration report of Callisto 100 SC Fumeaux J. 2014	<b>Accepted/Data Gap</b> There are no data on analysing relevant



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.5)	the a.s. content in the formulation: analytical method SF-424/1.		be formed in trace amounts during the chemical synthesis of mesotrione technical material, the relevant impurity 1,2-dichloroethane is a process solvent used during the chemical synthesis of mesotrione technical material however cannot be formed from mesotrione or from other formulation components of A12739A; storage stability data for impurities in formulated product A12739A is therefore not required.		A12739A_10499	impurities (R287431, R287432, 1,2-dichloroethane) of mesotrione in the PPP in the ambient two years storage stability study. Adequate data should be submitted by the applicant. Nevertheless, the missing data may be evaluated in the post registration at national level.
Shelf life in months (if less than 2 years) (KCP 2.7.6)			N/A			
Wettability (KCP 2.8.1)	Not required for this formulation					<b>Accepted</b>
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production: 09.2020 Batch No: CHR/12	0.075% 0 ml after 1min and 0 ml after 12 min- 0.05% 0 ml after 1min and 0 ml after 12 min 0.5% 0 ml after 1min and 0 ml after 12 min 0.75% 0 ml after 1min and 0 ml after 12 min 1% 0 ml after 1min	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable limits : max 60 mL foam after 1 minute. The above mentioned criteria were met.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																												
			and 0 ml after 12 min 5% 0 ml after 1min and 0 ml after 12 min																															
	CIPAC MT 47.2	99.5 g/L mesotrione SC (A12739A)	The foam persistence of A12739A was measured at two different concentrations: 0.75 % in CIPAC water D: after 10s 82 ml after 1 min 0 ml after 3 min 0 ml after 12 min 0 ml 0.3 % in CIPAC water D: after 10s 0 ml after 1 min 0 ml after 3 min 0 ml after 12 min 0 ml The results demonstrate that foam generated from the dilution of A12739A dissipates rapidly and will not interfere with the effective spray application of the formulation	N	Registration report of Callisto 100 SC Khot S.B. 2012 A12732A_10006	Accepted																												
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Name of test item: CHR/H/MEZZO 100 SC Active ingerdient: Mesotrione A.I. CAS: 104206-82-8 Date of production:09.2020 Batch No: CHR/12	<table><tr><td colspan="2">Initial preparation:</td></tr><tr><td>0.075%</td><td>99.82%</td></tr><tr><td>0.05%</td><td>99.08%</td></tr><tr><td>0.5%</td><td>88.93%</td></tr><tr><td>0.75%</td><td>87.62%</td></tr><tr><td>1%</td><td>86.51%</td></tr><tr><td>5%</td><td>92.06%</td></tr></table> <table><tr><td colspan="2">After accelerated storage:</td></tr><tr><td>0.075%</td><td>101.22%</td></tr><tr><td>0.05%</td><td>100.42%</td></tr><tr><td>0.5%</td><td>80.87%</td></tr><tr><td>0.75%</td><td>86.48%</td></tr><tr><td>1%</td><td>80.94%</td></tr><tr><td>5%</td><td>80.19%</td></tr></table>	Initial preparation:		0.075%	99.82%	0.05%	99.08%	0.5%	88.93%	0.75%	87.62%	1%	86.51%	5%	92.06%	After accelerated storage:		0.075%	101.22%	0.05%	100.42%	0.5%	80.87%	0.75%	86.48%	1%	80.94%	5%	80.19%	Y	Arévalo E. Study code: BF-49/20	Accepted Suspensibility/dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. The content of active substance - Mesotrione - in suspension was determined by High Performance Liquid Chromatography (HPLC) using reversed phase column with DAD detector at wavelength
Initial preparation:																																		
0.075%	99.82%																																	
0.05%	99.08%																																	
0.5%	88.93%																																	
0.75%	87.62%																																	
1%	86.51%																																	
5%	92.06%																																	
After accelerated storage:																																		
0.075%	101.22%																																	
0.05%	100.42%																																	
0.5%	80.87%																																	
0.75%	86.48%																																	
1%	80.94%																																	
5%	80.19%																																	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						measuring 220 nm and external standard. The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met.
	CIPAC MT 184	99.5 g/L mesotrione SC (A12739A)	The suspensibility of A12739A was measured at two different concentrations, gravimetrically and by active ingredient analysis: Gravimetrically: Concentration 0.75 % in CIPAC water D at 30°C: 98 % Concentration 0.3 % in CIPAC water D at 30°C: 100 % Active ingredient analysis: Concentration 0.75 % in CIPAC water D at 30°C: mesotrione: 77 % Concentration 0.3 % in CIPAC water D at 30°C: mesotrione: 93 %	N	Registration report of Callisto 100 SC Khot S.B. 2012 A12732A_10006	<b>Accepted</b>
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production: 09.2020	<b>Initial preparation:</b> 67.96 %	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water.  The content of active
			<b>After accelerated storage:</b> 72.01 %			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No: CHR/12				substance - Mesotrione - in dispersion was determined by High Performance Liquid Chromatography (HPLC) using reversed phase column with DAD detector at wavelength measuring 220 nm and external standard. The method was developed and validated in GLP laboratory. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %. The criteria were met.
	CIPAC MT 160	99.5 g/L mesotrione SC (A12739A)	The spontaneity of A12739A was measured gravimetrically and by active ingredient analysis; concentration of 5 % v/v in CIPAC Water D at a temperature of 30 °C. Gravimetrically: 94 % Active ingredient analysis: mesotrione 88 %	N	Registration report of Callisto 100 SC Khot S.B. 2012 A12732A_10006	<b>Accepted</b>
Dispersion stability (KCP 2.8.3.3)	Not required for this formulation					<b>Accepted</b>
Degree of dissolution and dilution stability	Not required for this formulation					<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.4)						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	99.25 g/L mesotrione SC (A12739A)	The particle size distribution of a dispersion of A12739A was recorded using a laser diffraction instrument. The distribution results revealed: 10 % of particles were below 1.15 µm 50 % of particles were below 7.18 µm 90 % of particles were below 17.5 µm	Y	Registration report of Callisto 100 SC Khot S.B. 2012 A12732A_10008	<b>Accepted</b>
Wet sieve test (KCP 2.8.5.1.2)	CPAC MT 185	Name of test item: CHR/H/MEZZO 100 SC Active ingredient: Mesotrione A.I. CAS: 104206-82-8 Date of production: 09.2020 Batch No: CHR/12	<b>Initial preparation:</b> 0.00%	Y	Arévalo E. Study code: BF-49/20	<b>Accepted</b> Wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The criteria were met.
			<b>After accelerated storage:</b> 0.00%			
	CIPAC MT 185	99.5 g/L mesotrione SC (A12739A)	< 0.01 % was retained on a 75 µm sieve.	N	Registration report of Callisto 100 SC Khot S. B. 2012 A12732A_10006	<b>Accepted</b>
Dust content (KCP 2.8.5.2.1)	Not required for this formulation					<b>Accepted</b>
Particle size of	Not required for this formulation					<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
dust (KCP 2.8.5.2.2)						
Attrition (KCP 2.8.5.3)	Not required for this formulation					Accepted
Hardness and integrity (KCP 2.8.5.4)	Not required for this formulation					Accepted
Emulsifiability (KCP 2.8.6.1)	Not required for this formulation					Accepted
Emulsion stability (KCP 2.8.6.2)	Not required for this formulation					Accepted
Re-emulsifiability (KCP 2.8.6.3)	Not required for this formulation					Accepted
Flowability (KCP 2.8.7.1)	Not required for this formulation					
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Name of test item: CHR/H/MEZZO 100 SC Active ingerdient: Mesotrione A.I. CAS: 104206-82-8 Date of produc- tion:09.2020 Batch No: CHR/12	<b>Initial preparation:</b> R = 4.16%, R' = 0.78%	Y	Arévalo E. Study code: BF-49/20	<b>Accepted*</b> The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. Acceptable limits : Maximum 5 % residue. The criteria were met. * With respect to rinsed residue (R') the reported result is above the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						normally accepted value (max. 0.25% rinsed residue). See comments below for pourability - Registration report of Callisto 100 SC.
			<b>After accelerated storage:</b> R = 4.57%, R' = 0.71%			<b>Accepted*</b> The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. Acceptable limits : Maximum 5 % residue. The criteria were met. * With respect to rinsed residue (R') the reported result is above the normally accepted value (max. 0.25% rinsed residue). See comments below for pourability - Registration report of Callisto 100 SC.
	CIPAC MT 148	99.5 g/L mesotrione SC (A12739A)	Pourability: Pour residue: 4.1% Rinsed residue: 0.5 % With respect to rinsed residue the reported result is above	N	Registration report of Callisto 100 SC Khot S. B. 2012	<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>the normally accepted value. The pourability method recommended and used for the assessment (CIPAC MT148) gives, however, only an estimate of the actual rinsed residue that would occur in a practical situation and is almost certainly an over estimate. Pack rinsing in the field will inevitably be performed more vigorously than that represented by the inversion technique specified in CIPAC MT148 and that rinsing will normally be performed to completion.</p> <p>To demonstrate this effect the residual concentration of A12739A, in sales packs (1litre PET and 5litre HDPE), after the commonly employed field recommendation of triple hand rinsing, was determined. The results of that work show that a maximum of 0.0005% of the original weight of product remains in the sales container after triple hand rinsing thus demonstrating that in actual application the rinsed residue is negligible and would not pose any risk if the packs were rinsed and disposed of as recommended.</p> <p>Furthermore, a 20litre HDPE pack filled with A12739A had its pour and rinsed residue measured before and after two years storage at 25°C. Again, triple rinsing was able to reduce the residues to acceptable levels.</p>		<p>A12732A_10006  Buser H-P. 2005  ZA1296/1855  Wochner F. 2007  ZA1296/2594</p>	
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for this formulation					Accepted
Physical compatibility of tank mixes (KCP 2.9.1)	Not required.					Accepted
Chemical compatibility of	Not required.					Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
tank mixes (KCP 2.9.2)						
Adhesion to seeds (KCP 2.10.1)	Not required for this formulation					<b>Accepted</b> Not required for this formulation
Distribution to seed (KCP 2.10.2)	Not required for this formulation					<b>Accepted</b> Not required for this formulation
Other/special studies (KCP 2.11) Equipment cleaning	proprietary method	99.5 g/L mesotrione SC (A12739A)	A12739A (mesotrione SC (100)). After applying the cleaning procedure, 0.16 % residue was found in the refilled spray tank. Despite the fact that the residue in the refilled spray tank is 0.16 %, relative to the initial spray broth, the absolute turbid-ity value (0.713 NTU) in the refilled spray tank is sufficient-ly small. Therefore, the applied rinsing procedure can be considered as sufficient.	N	Registration report of Callisto 100 SC Kundel P. 2012a	<b>Accepted</b>

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

**Table 4.1-1: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm

Closure:	screw cap with seal
Capacity	564 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-7: Packaging information**

Type	JAR
Material:	HDPE
size: approximate diameter/height	79/80 mm / 138 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	510 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-8: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal

Capacity	600 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-9: Packaging information**

Type	JAR
Material:	HDPE
size: approximate diameter/height	79/80 mm / 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-10: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-11: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-12: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-13: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-14: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-15: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-16: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	84 mm± 2 mm/248.2 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-17: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	cap with seal
Capacity	1200 ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-18: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-19: Packaging information**

Type	JAR
Material:	HDPE
size: approximate diameter/height	108/110mm / 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-20: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-21: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-22: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-23: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-24: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-25: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-26: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-27: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-28: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	310,5 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml



Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-29: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-30: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-31: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	231,5mm± 5 mm193mm ± 5 mm
Opening:	115 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-32: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm

Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-33: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-34: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-35: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-36: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	377,7 mm± 5 mm/239,5± 5 mm/178 mm ± 5 mm
Opening:	54 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-37: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	192±3 mm/228±7/313±7 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-38: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	185±2 mm/225±2/312±3 mm
Opening:	40.8 mm ± 0.3 mm
Closure:	screw cap with seal
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-39: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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**Table 4.1-40: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1.-41: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	376.3±3 mm/295±3mm/246±3mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-42: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	378±5 mm/288±5/258±5 mm
Opening:	53.7±1.5 mm
Closure:	screw cap with seal
Capacity	22000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-43: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	376±8 mm/257,5±5/376±8 mm
Opening:	52 mm± 3
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-44: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	257.5±6 mm/292±8/376±8 mm ± 5 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

According to guideline from Ministry of Agriculture and Rural Development (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) storage stability study can be extrapolated to new packaging material HDPE/PA, HDPE/F, HDPE/EvOH from provided and evaluated storage stability studies of packing HDPE. Therefore, no further studies are required for the additional packaging materials.

**Table 4.1-45: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-46: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-47: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-48: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	69 mm ± 2 mm/186.5 mm ± 2 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-49: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-50: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-51: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	88 mm $\pm$ 2 mm/238 mm $\pm$ 2 mm
Opening:	50 mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-52: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 $\pm$ 3 mm/84 $\pm$ 1.5mm
Opening:	50 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-53: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 $\pm$ 3 mm/84 $\pm$ 1.5mm
Opening:	50 mm $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-54: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	234 mm $\pm$ 2 mm/88.5mm $\pm$ 2 mm
Opening:	42 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-55: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-56: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-57: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-58: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded



UN/ADR	compliant
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**Table 4.1-59: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-60: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-61: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-62: Packaging information**

Type	CANNISTER
Material:	HDPE/PA
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-63: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	305mm/193 mm/142 mm $\pm$ 5 mm
Opening:	63 mm minimum $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	10000 ml $\pm$ 150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-64: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	377,7mm/178 mm/239,5 mm $\pm$ 5 mm
Opening:	54 mm min $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	10000 ml $\pm$ 150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-65: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	63.5 $\pm$ 1 mm/126 $\pm$ 1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 $\pm$ 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-66: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	63.5 $\pm$ 1 mm/126 $\pm$ 1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 $\pm$ 12.5 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-67: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-68: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-69: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-70: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal

Capacity	585 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-71: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-72: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-73: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1170 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-74: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm

Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-75: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-76: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-77: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-78: Packaging information**

Type	BOTTLE
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Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	54,2 mm $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-79: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	63.4 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-80: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	67,5 mm $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-81: Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	54,2 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-82: Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	63,4 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-83: Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	67,5 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-84: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	240 $\pm$ 2 mm/179 $\pm$ 2mm/375 $\pm$ 3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-85: Packaging information**

Type	BOTTLE
Material:	HDPE/ EVOH
Body diameter / total height:	62,50 +- 0,50 / 126,50 +- 1,50
External thread diameter:	49,65 +- 0,35
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	N/A

**Table 4.1-86: Packaging information**

Type	BOTTLE
Material:	HDPE/ EVOH
Body diameter / total height:	59 +- 1 mm / 143 +- 1 mm
External thread diameter:	41.7 +- 0,4 mm
Closure:	screw cap with seal
Capacity	310 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

**Table 4.1-87: Packaging information**

Type	BOTTLE
Material:	HDPE/ EvOH
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	42±3 mm
Closure:	screw cap with cutter
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-88: Packaging information**

Type	BOTTLE
Material:	HDPE/ EvOH
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-89: Packaging information**

Type	BOTTLE
Material:	HDPE/ EvOH
size:	69 mm ±1 mm/190 mm ±1.5 mm
Opening:	49.5 mm ±0.3 mm



Closure:	screw cap with seal
Capacity	579 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-90: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-91: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-92: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	50 mm ± 3 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-93: Packaging information**

Type	BOTTLE
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Material:	HDPE/EvOH
size:	242±1.5 mm/88.5±1mm
Opening:	49.5 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	1200± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-94: Packaging information**

Type	CONTAINER
Material:	HDPE/EvOH
size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-95: Packaging information**

Type	CANNISTER
Material:	HDPE/EvOH
size:	142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm
Opening:	63.3 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-96: Packaging information**

Type	CONTAINER
Material:	HDPE/EvOH
size:	195 mm ± 2 mm/225mm± 2 mm/306mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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**Table 4.1-97: Packaging information**

Type	CONTAINER
Material:	HDPE/EvOH
size:	375 mm $\pm$ 2 mm/290mm $\pm$ 2 mm/245mm $\pm$ 2 mm
Opening:	85mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP.2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1	Arévalo E.,	2021	CHR/H/MEZZO 100 SC Determination of physicochemical properties of the preparation Study code: BF-49/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	„Chemiroł” Sp. z o.o.
KCP 2.2.1	Ołowski G.,	2023	MEZI 100 SC Determination of explosive properties Study code: BW-07/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	„Chemiroł” Sp. z o.o.
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Pachnicki P.	2023	MEZI 100 SC Determination of flash point, auto-ignition temperature and oxidizing properties Study code: BC-31/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	„Chemiroł” Sp. z o.o.

**List of data submitted by the applicant and relied on, but evaluated before in Callisto 100 SC**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 2.2 KCP 2.3	Jackson W.	2017	A12739A - Safety Study Syngenta Crop Protection AG, Basel, Switzerland Syngenta Technology & Engineering, Huddersfield UK, HT17/506 GLP not published Syngenta File No A12739A_11137	N	Syngenta
KCP 2.7	Fumeaux J.	2014	A12739A - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Munchwilen, Switzerland, 300022324 Not GLP not published Syngenta File No A12739A_10499	N	Syngenta

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 2.6.1	Halarnakar R.	2012	A12739A - Chemical characterization before storage of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11364 GLP not published Syngenta File No A12732A_10001	N	Syngenta

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 2.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.5.1.2 KCP 2.8.7.2	Khot S.	2012	A12739A - Technical properties of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMN10807 Not GLP not published Syngenta File No A12732A_10006	N	Syngenta
KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.8.3.2 KCP 2.8.5.1.1	Khot S.	2012a	A12739A - Physical properties of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11365 GLP not published Syngenta File No A12732A_10008	N	Syngenta
KCP 2.7.2	Kundel P.	2012	A12739A - Storage stability and shelf life statement (8 weeks 40 -C) in packaging made of HDPE Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Munchwilen, Switzerland, 10512883 Not GLP not published Syngenta File No A12739A_10446	N	Syngenta
KCP 2.8.7.2	Buser H.P.	2005	A-12739 A - Mesotrione formulation (YF11645) - Pourability data Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Not GLP not published Syngenta File No ZA1296/1855	N	Syngenta
KCP 2.8.7.2	Wochner F.	2007	A12739A - Gravimetric assessment of residue and rinsed residue (triple rinsing) after storage (2 years 25-C) in packaging made of HDPE Syngenta Crop Protection AG, Basel, Switzerland	N	Syngenta

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
			Syngenta Crop Protection Munchwilen AG, Munchwilen, Switzerland, 10068880 Not GLP not published Syngenta File No ZA1296/2594		
KCP 2.11	Kundel P.	2012a	A12739A The Effectiveness of the Spray Tank Cleaning Procedure, Final Report Syngenta Crop Protection AG, Switzerland Not GLP not published Syngenta File No 10493941	N	Syngenta

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>

**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>



## Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

### A 2.1 Mesotrione

No additional data have been generated on the active substance Mesotrione.

## Appendix 3 Content of active ingredient and properties before and after storage for eight weeks at 40°C in HDPE packaging

Content of active ingredient before and after storage for eight weeks at 40°C in HDPE packaging Active Ingredient	Storage Conditions	Content of control sample	Content of test sample
mesotrione	Initial	99.5 g/l	- -
mesotrione	8 weeks below -10 °C	99.2 g/l	- -
mesotrione	8 weeks 40 °C	- -	96.6 g/l

### Observations and Conclusion

A relative decomposition of 2.65 % of mesotrione was observed.

Physical and technical properties before and after storage for eight weeks at 40°C in HDPE packaging Test Description	Method	Initial Results	Results after 8 weeks 40 °C
<b>Color</b>	Visual	yellow brown	yellow brown
<b>Odor</b>	Organoleptic	octanol like	octanol like
<b>Physical State</b>	Visual	liquid	liquid
<b>Appearance</b>	Visual	- - -	no claying, easily redispersible
<b>pH Value</b> Concentration: 1 % Deionized Water	CIPAC MT 75.3	2.9	2.9
<b>pH Value</b> undiluted	CIPAC MT 75.3	2.8	2.7
<b>Acidity</b> Calculated as H <sub>2</sub> SO <sub>4</sub>	CIPAC MT 191	2.57 %	2.76 %
<b>Relative Density</b> Temperature: 20 °C	OECD 109	1.095 g/cm <sup>3</sup>	1.095 g/cm <sup>3</sup>
<b>Viscosity</b> Temperature: 20 °C Shear Rate: 20 s <sup>-1</sup> Shear Rate: 80 s <sup>-1</sup> Temperature: 40 °C Shear Rate: 20 s <sup>-1</sup> Shear Rate: 80 s <sup>-1</sup>	CIPAC MT 192	756 mPa.s 576 mPa.s 402 mPa.s 244 mPa.s	810 mPa.s 589 mPa.s 412 mPa.s 247 mPa.s
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	< 0.01 %	< 0.01 %
<b>Persistent Foaming</b> CIPAC Water D Waiting Period: 1 min.	CIPAC MT 47.2	0 ml 0 ml	0 ml 0 ml

Concentration: 0.75 % Concentration: 0.3 %			
<b>Pourability</b> Pour Residue Rinsed Residue	CIPAC MT 148	4.1 % 0.5 %	4.5 % 0.7 %
<b>Suspensibility</b> Concentration: 0.75 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione	CIPAC MT 184 (chemical assay)	77 %	77 %

#### Packaging Evaluation after storage for eight weeks at 40°C in HDPE packaging

Evaluation Criteria	Results after 8 weeks 40 °C
Color change of the packaging	none
Odor (noticeable before opening the packaging)	none
Panelling of the test container	none
Ballooning of the test container	none
Pimples on the test container	none
Cracks in the test container	none
Tightness of the test container	tight
Reclosability of closure	reclosable
Tightness of closure	tight
Weight change (gross weight)	0.03 % weight loss
Permeation through the container walls	none

#### Observations and Conclusion

The packaging material proved to be resistant to its content.

### Appendix 4 Content of active ingredients and properties before and after storage for two years at 20°C in HDPE packaging

Content of active ingredient before and after storage for two years at 20°C in HDPE packaging Active Ingredient	Initial	2 years below -10 °C (control sample)	2 years 20 °C (test sample)
mesotrione	99.5 g/l	100 g/l	98.9 g/l

#### Observations and Conclusion

All the values are well within analytical error and show no decomposition.

Physical and technical properties before and after storage for two years at 20°C in HDPE packaging Test Description	Method	Initial Results	Results after 2 years 20 °C
Color	Visual	yellow brown	yellow brown
Odor	Organoleptic	octanol like	octanol like
Physical State	Visual	liquid	liquid
Appearance	Visual	- - -	no claying, easily redisper-

			sible
<b>pH Value</b> Concentration: 1 % Deion-ized Water	CIPAC MT 75.3	2.9	2.9
<b>pH Value</b> Undiluted	CIPAC MT 75.3	2.8	2.8

Test Description	Method	Initial Results	Results after 2 years 20 °C
<b>Acidity</b> Calculated as H <sub>2</sub> SO <sub>4</sub>	CIPAC MT 191	2.57 %	2.81 %
<b>Relative Density</b> Tem-perature: 20 °C	OECD 109	1.095 g/cm <sup>3</sup>	1.094 g/cm <sup>3</sup>
<b>Viscosity</b> Temperature: 20 °C Shear rate: 20 s-1 Shear rate: 80 s-1	CIPAC MT 192	756 mPa.s 576 mPa.s	853 mPa.s 598 mPa.s
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	< 0.01 %	< 0.01 %
<b>Persistent Foaming</b> CIPAC Water D Wait-ing Period: 1 min. Con-centration: 0.75 % Con-centration: 0.3 %	CIPAC MT 47.2 (chemical assay)	0 ml 0 ml	0 ml 0 ml
<b>Pourability</b> Pour Resi-due Rinsed Residue	CIPAC MT 148	4.1 % 0.48 %	4.9 % 0.77 %
<b>Suspensibility</b> Concen-tration: 0.75 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione	CIPAC MT 184 (chemical assay)	77 %	78 %
<b>Suspensibility</b> Concen-tration: 0.3 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione	CIPAC MT 184 (chemical assay)	93 %	91 %
<b>Spontaneity of Disper-sion</b> CIPAC Water D Temperature: 30 °C mesotrione	CIPAC MT 160 (chemical assay)	88 %	88 %

### Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

### Packaging Evaluation after storage for two years at 20°C in HDPE packaging

Evaluation Criteria	Results after 2 years 20 °C
Color change of the packaging	none
Odor (noticeable before opening the packag-ing)	none
Panelling of the test container	none
Ballooning of the test container	none
Pimples on the test container	none

Cracks in the test container	none
Tightness of the test container	tight
Reclosability of closure	reclosable
Tightness of closure	tight
Weight change (gross weight)	0.02 % weight loss
Permeation through the container walls	none